PATENT COOPERATION TRE Y

From the
ERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION CONCERNING INFORMAL COMMUNICATIONS WITH THE APPLICANT

(PCT Rule 66.6)

Sent by fax in advance

Date of mailing *(day/month/year)*	20.01.2005
Applicant's or agent's file reference: P68878PC00	**REPLY DUE** within 1 month(s) from the above date of mailing
International application No: PCT/IB 03/06399	International filing date *(day/month/year)*: 05.12.2003
Applicant: UNIVERSITY OF ULSTER et al	

An informal communication took place on 12.01.2005,between the International Preliminary Examining Authority and the applicant / the agent.

Invitation pursuant to Rules 66.2 c), 66.3 and 66.4 of the PCT

Further examination of the international application has revealed that the application fails to meet the requirements of the PCT and the Regulations as explained in the attached note (Form PCT/IPEA/428).

The Applicant is hereby **invited,** within the time limit indicated above, **to submit a written reply** accompanied by amendments.

If no reply is submitted, the international preliminary examination report will reflect the opinion expressed by this Authority.

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Your Ref : PCT/IB03/006399
Our Ref : P68878PC00/ljc/sb

By Facsimile & Courier [No of Pages: 13] 15 February, 2005.
00-49-30 2 59 01 840

Dear Sirs,

International Application No. PCT/IB03/006399
"Wound mapping system"
University of Ulster at Coleraine

In response to the Communication dated 20 January, 2005, please find enclosed* herewith an amended set of claims 1-29. To facilitate the Examiner, the typescript amended version is also enclosed* herewith.

The Applicant appreciates the opportunity for filing further observations. The examiner indicated that he now considers D3 to be the most pertinent piece of prior art, due to the presence of the sentence "The system may also include a cardiac mapping system 47" at col. 6, lines 32-33. The examiner is presumably interpreting this as referring to a visual representation of the physical extent of the heart tissue. However, this is not a correct interpretation of the term "cardiac mapping" in the context of D3.

Before discussing D3, however, we would point out that we have amended claim 1 to remove the reference to visual mapping and redrafted claim 1 in terms of "means for presenting at least one value representing a physical characteristic of at least one region of tissue". The basis for this amendment is to be found at, inter alia, page 13 lines 5-9 which makes it quite clear that mapping is not an essential feature to determine area, and page 7 lines 20-26 which make it equally clear that the invention is applicable to the measurement of physical characteristics generally. Area measurement and visual mapping have therefore been relegated to new claims 2 and 3.

Turning now to a consideration of D3, "cardiac mapping" is a broad term that covers several modes of mapping such as body surface, endocardial, and epicardial mapping. The "cardiac mapping" referred to in D3 is more correctly called "body surface (potential) mapping", as opposed to other approaches which involve electrodes put directly on/in the heart. "Body surface (potential) mapping" involves the recording of regional electrophysiological

information by analysis of surface potentials to give a complete picture of the effects of the currents from the heart on the body surface – see Braunwald, Heart Disease, 4th ed) and

http://www.use.hcn.com.au/subject.%60Body%20Surface%20Potential%20Mapping%60/home.html

It is therefore the mapping on the body surface of projections (potentials) of the underlying electrical activity of the heart. It is an electrical activity map and not a physical map of the heart nor does it refer to any physical characteristic of the heart. See also:

http://www.um.savba.sk/lab_21/maps_en.htm#potential%20mapping

This is also clear from D3 as it correctly indicates that "cardial spatial mapping" is effectively an extension of the "basic" ECG procedures. See, for example, col. 2 lines 28-35:

> "Many abnormal cardiac conditions escape detection with present ECG monitoring or diagnostic systems which employ up to twelve leads. Cardiac spatial mapping enhances the probability that such conditions will be detected and is a procedure in which a multiplicity of voltage readings are made simultaneously from a large number of different sites on the patient's chest."

and col. 8 lines 55-66:

> "Applications besides those discussed above wherein large numbers of electrodes are desirable are cardiac spatial mapping and multi-lead ECG monitoring. For cardiac mapping, an electrode pad, such as that illustrated in FIG. 3, or one having a greater number of electrodes would provide the requisite number of sites. For multi-lead ECG monitoring, such as twelve-lead monitoring, the electrode of FIG. 3 or one having a greater number of electrodes would provide sufficient redundant electrodes so that all of the leads can be monitored even if one or a few electrodes were loose or not making proper contact."

This cardiac spatial mapping is the "cardiac mapping" referred to at col. 6, lines 32-33.

Therefore, D3 describes the monitoring of natural electrical impulses from a patient's heart, NOT the measuring of the electrical properties of tissues underlying the electrodes and the mapping of their key features or otherwise using the measured information to determine a physical characteristic such as area or shape. D3 does mention the possible use of their system to measure cardiac output using an impedance technique. This is a type of impedance plethysmography in which bioelectrical impedance is measured between electrodes generally positioned around the neck and around the lower thorax. It is used principally to calculate stroke volume and cardiac volume, but it is also related to myocardial contractility, thoracic fluid content, and circulation to the extremities. This has nothing to do with impedance mapping.

In summary, the term "cardiac mapping" in D3 refers to an "electrical" map, rather than a physical map or any other physical characteristic such as area.

Claim 20 (previously 18) has been amended consistent with claim 1.

Form 1037 is enclosed by courier only.

Yours faithfully

Lindsay J. Casey
Representative

Claims

1. A tissue measurement system comprising a two-dimensional array of test electrodes for application to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and means for presenting at least one value representing a physical characteristic of at least one region of tissue based upon the measured electrical characteristics.

2. A system as claimed in claim 1, wherein the physical characteristic is area.

3. A system as claimed in claim 2, wherein the presenting means presents a plurality of values on a display device to provide a visual map representing the physical extent of the region of tissue.

4. A system as claimed in claim 1, 2 or 3, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

5. A system as claimed in claim 4, wherein the array of electrodes is a rectangular array.

6. A system as claimed in claim 4 or 5, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

7. A system as claimed in claim 6, wherein the gel is hydrogel.

8. A system as claimed in any one of claims 4 to 7, wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

9. A system as claimed in any preceding claim, wherein the two-dimensional array comprises at least 25 test electrodes.

10. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

11. A system as claimed in any preceding claim, wherein the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

12. A system as claimed in claim 11, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

13. A system as claimed in claim 12, wherein the reference electrode is also disposed on the flexible backing of insulating material.

14. A system as claimed in claim 13, wherein a single reference electrode is common to a plurality of test electrodes.

15. A system as claimed in claim 13, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.

16. A system as claimed in any one of claims 11 to 15, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.

17. A system as claimed in any one of claims 11 to 16, wherein for each test electrode a measurement is made at a plurality of different frequencies.

18. A system as claimed in any one of claims 11 to 17, wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.

19. A system as claimed in any preceding claim, wherein the array of test electrodes is incorporated into a wound dressing.

20. A method of measuring tissue comprising applying a two-dimensional array of test electrodes to the surface of tissue under investigation, measuring an electrical characteristic of the tissue underlying each test electrode, and presenting at least one value representing a physical characteristic of at

least one region of tissue based upon the measured electrical characteristics.

21. A method as claimed in claim 20, wherein the physical characteristic is area.

22. A method as claimed in claim 21, wherein a plurality of values are presented on a display device to provide a visual map representing the physical extent of the region of tissue.

22. A method as claimed in claim 20, 21 or 22, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

23. A method as claimed in claim 22, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

24. A method as claimed in any one of claims 20 to 23, wherein the two-dimensional array comprises at least 25 test electrodes.

25. A method as claimed in any one of claims 20 to 24, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

26. A method as claimed in any one of claims 20 to 25, wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode

applied to the organic body of which the tissue forms a part.

27. A method as claimed in claim 26, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

28. A method as claimed in claim 26 or 27, wherein for each test electrode a measurement is made at a plurality of different frequencies.

29. A method as claimed in any one of claims 20 to 28, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.